

# **REMARKS**

The Office Action mailed May 1, 2003, set a three-month shortened statutory period for response expiring August 1, 2003. Pursuant to the Petition for Extension of Time under 37 C.F.R. 1.136(a) submitted herewith, the period for reply is extended three months to November 1, 2003. This Request for Continued Examination is therefore timely filed.

Claims 2-4, 6-9, 11, 12, and 14-43 are in the application. All the claims stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Penners et al in view of Wong et al, Shell, and Maggi et al.

Claim 2 is amended to more specifically define the content of the composition.

Claim 4 is amended to recite the composition of claim 2 further containing a hydration promoter.

Claim 14 is amended to more particularly define the hydrophilic polymer in the composition of claim 4.

Thus, these amendments serve to more particularly define Applicants' invention and to further distinguish it from the prior art.

The Examiner characterizes Applicants' arguments submitted March 3, 2003, as a piecemeal analysis of the prior art urging that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. This is submitted to be a mischaracterization of Applicants' arguments.

Applicants have of course analyzed the references individually. How else could it have been determined what the references teach; and how else could it have been determined whether, as required by well-settled law, the prior art suggested the desirability of their combination, i.e., whether there was some teaching, suggestion, or incentive in one or more of the cited references, which would have led one skilled in the art to combine their teachings. *In re Geiger* 2 USPQ2d 1276; *In re Fine* 5 USPQ2d 1596; *ACS Hospital Systems, Inc. v. Montefiore Hospital* 221 USPQ 929; *In re Regel* 188 USPQ 136; *Ex parte Hiyamizu* 10 USPQ2d 1393. Having analyzed the references individually, Applicants then did, in fact, consider the references in combination as evidenced by several statements in Applicants' response, for example:

"That Wong et al recites long lists of polymers, excipients, and active ingredients absent from the disclosure of the primary reference in compositions that are

different from both those of the primary Penners et al reference and those here claimed, is simply not a teaching that would suggest modifying the teaching of Penners et al in such a way as to arrive at Applicants' claimed compositions. Hence, Wong et al adds nothing to Penners et al." (pp. 5-6);

"...nothing in the Shell reference, considered alone or in combination with Wong et al, would suggest modifying the Penners et al compositions to arrive at Applicants' compositions. Accordingly, Shell adds nothing to the primary Penners et al reference." (p. 6);

"...like the Wong et al and Shell references, the Maggi et al reference adds nothing to the primary Penners et al reference, and considered alone or in combination with Wong et al and/or Shell contains nothing that would suggest modifying the composition of Penners et al to arrive at Applicants' compositions." (p. 6)

and that each of the four cited references

"...discloses certain ingredients also contained in the instantly claimed compositions. However, all the compositions disclosed in the cited references differ from each other as well as from Applicants' compositions both in content and mode of functioning. The mere fact that individual ingredients of Applicants' compositions can be found listed in a collection of prior art references is not tantamount to a teaching of the means of assembling the ingredients so as to produce Applicants' compositions having the properties and uses described therefor. Accordingly, there is nothing in the cited references, whether considered individually or in any combination, which would have taught or suggested the compositions here-claimed." (p. 6.)

The Examiner has urged that one skilled in the art would have been motivated to combine the teachings of Penners et al and Wong et al on the basis of the holding in *In re Kerkhoven* (205 USPQ 1069.)

It is submitted that Kerkhoven is inapposite to the instant fact situation and the Examiner's reliance thereon is misplaced. The relevant claims at issue in Kerkhoven were directed to a method of producing particulate detergent compositions containing a mixture of anionic and nonionic detergents by mixing an independently spray-dried anionic detergent with

an independently spray-dried nonionic detergent. The court held that it was *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. That is clearly not the situation in the present case. Combining the composition of Penners et al and Wong et al would presumably give a product containing two different compositions each acting independently; but it would not, and in fact could not, give Applicants' claimed composition. As previously pointed out, Penners et al teach that a mixture of specific polymers selected from different polymer families is essential to operability, whereas, Applicants' compositions contain a single polymer or a mixture of polymers selected from the same polymer family. Like Penners et al, Wong et al also teach the need for a mixture of different polymers not required in Applicants' compositions. Moreover, the Wong et al dosage forms require a band of rigid or semi-rigid insoluble material circumscribing a portion of the polymer matrix to ensure adequate gastric residence time. No such band is present in Applicants' compositions. Combining the compositions disclosed by Penners et al and Wong et al simply would not form Applicants' composition.

To urge, in the alternative, that there is some suggestion or motivation to combine the teachings of the references, i.e., that there is some suggestion in Wong et al to modify Penners et al, or vice versa, so as to arrive at Applicants' invention is tantamount to urging that there is some suggestion in the references that those elements taught therein to be essential to operability, e.g., the mixture of polymers from different families in Penners et al and the band of insoluble material in Wong et al, (both absent in Applicants' compositions) are in fact unnecessary. It is not seen how any such suggestion can be derived from either Penners et al or Wong et al absent the hindsight benefit of Applicants' disclosure.

Nor do Shell and Maggi et al alter the situation. In order to achieve sufficient gastric residence time, Shell relies on a chemical agent that induces the fed mode. No such agent is present in Applicants' compositions. It is not seen how the combined teachings of Shell, Penners et al, and Wong et al would have suggested Applicants' compositions which do not contain any of the elements taught by the references to be essential to achieving controlled release in the stomach.

Maggi et al disclose multi-layer alfuzosin-containing tablets, at least one of which layers acts as a barrier to the passage of alfuzosin. The Examiner calls attention to the disclosure of

various polymers that may be used in the alfuzosin tablets, and that Maggi et al does not require a combination of polymers from different categories. Actually, the reference discloses a lengthy list of polymers and families of polymers from which one might choose, and while it might be argued that it would have been obvious to try a single polymer selected from the recited list of polymer families or a mixture of polymers from one of those families, "obvious to try" is not the standard of 35 U.S.C. § 103. *In re Goodwin* 198 USPQ 1; *In re Antonie* 195 USPQ 6. Nowhere does Maggi et al provide any suggestion as to how its combination with Penners et al, Wong et al, and Shell would lead to Applicants' compositions, except perhaps by viewing the references retrospectively in the light of Applicants' disclosure.

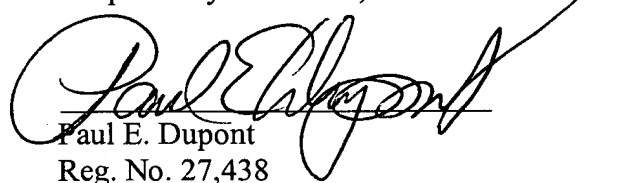
The Examiner appears to have selected from the cited references only so much as will support his position while ignoring what the references as a whole fairly teach one skilled in the art. It is submitted that this picking and choosing from the references amounts to an impermissible hindsight reconstruction of the claimed invention in the light of Applicants' own disclosure. The references, viewed by themselves and not in retrospect once Applicants' disclosure is known, must suggest doing what Applicants have done. It is submitted that the cited references, viewed by themselves at the time the instant invention was made and considered as a whole for what they fairly teach to one skilled in the art, would not have suggested Applicants' invention, and accordingly, the rejection based thereon should be withdrawn.

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance and such actions are earnestly solicited.

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Respectfully submitted,

  
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